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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,485	09/15/2000	Nobuya Sato	197129US0PCT	7267

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[REDACTED] EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	15

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/623,485	SATO ET AL.
	Examiner	Art Unit
	Isis Ghali	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 January 2003.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3 and 7-23 is/are pending in the application.
- 4a) Of the above claim(s) 11-23 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3 and 7-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                      | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                             | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7, 11</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

The receipt is acknowledged of applicants' election, filed 01/23/2003.

### *Election/Restrictions*

1. Applicant's election with traverse of Group I, claims 1-3, 7-10 in Paper No. 14 is acknowledged. The traversal is on the ground(s) that:

- Unity of invention does exist between Groups I and II. The office has not explained why each group lacks unity and has not specifically described the unique special technical features in each group.
- The examiner has not set forth any evidence whatsoever that the oily ingredient is the inventive step of Group I.
- The office fails to offer no references on which the conclusion of distinction is based, i.e. the sheet of Group I can be produced by another process such as impregnation of the medical ingredient into the sheet, not requiring mixing, calendaring or kneading as required by Group II.
- The search of all claims would not impose a serious burden on the office.

This is not found persuasive because:

- Unity of inventions does not exist between Groups I and II because the product of the Group I requires composition comprising three elements: thermoplastic resin, medical ingredient and oily ingredient, while the process of Group II only

requires thermoplastic resin and medical ingredient, and that would result in a different product. Thus, no commonality in the product of Group I and the product produced by the process of Group II that lack the oily ingredient which may impart different properties on the final product. Further, the product of Group I can be produced by a process different from the process of Group II such as simple impregnation of a thermoplastic sheet with the medical ingredient and the oily ingredient.

- The examiner notes that the oily ingredient contributes to the inventive step of Group I, it is part of the claimed invention and it is a distinguishable factor between the two groups and makes the product produced by the process of Group II distinct from the product of Group I.
- The conclusion of distinction is based on the set forth facts, as well as on the following prior art: US 6,063,397 that teaches a method of making a sheet comprising thermoplastic resin, medical ingredient and oily ingredient by impregnated the thermoplastic sheet by the other ingredients followed by drying the sheet (col.21, lines 45-50; col.22, lines 2-4).
- The search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, no reason to expect the search to be un-extensive since the patent examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility

of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present two distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 11-23 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

***Continued Examination Under 37 CFR 1.114***

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/23/2003 has been entered..

***Priority***

4. Continuity as a 371 of PCT/JP99/00660 should be entered following the title of the invention or as the first sentence of the specification.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,063,379 ('397). *Fowler et al.*

The currently pending claim 1 recites a sheet comprising ingredient (A) that is 100 parts by weight of at least thermoplastic resin; ingredient (B) that is 0.01 to 200 parts by weight of medical ingredient; and at least one oily ingredient.

US '397 teaches a sheet (col.7, lines 24-27) comprising:

Polyolefins: nylon 6, nylon 66, polyethylene terephthalate or polyvinyl acetate that are disclosed by applicants as thermoplastic resin, (col.col5, lines 26, 49-63);

Active ingredients to be delivered to the skin or hair: anti-wrinkles, anti-inflammatory agents (col.17, lines 16-17; col.18, line 1; col.26, lines 49-56);

Agent selected from: mineral oils, vegetables oil, hydrogenated vegetable oil, alcohol esters, monoester and diester of fatty acids, and hydrocarbons that are disclosed by applicants as oily ingredients (col.13, line60-col.14, line 35); and

Polyethylene and polypropylene and polyurethane that are disclosed by applicants as hard segment elastomer, and polyester that is disclosed by applicants as soft segment elastomer, and mixtures thereof (col.5, lines 26, 49-63).

The reference does not teach anywhere that the film has an adhesive layer and that meets the limitation of claim 2 as claim 2 recites that the sheet comprises no adhesive layer.

The reference differs from the instant claims because it does not teach the amounts of the different ingredients and the modulus.

It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect, such as the modulus. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the ratios and weight percents of the thermoplastic resin and the active ingredient instantly claimed are not considered to impart a patentable distinction absent evidence showing unexpected and superior results. The prior art teaches the property of delivering active ingredients to the skin or hair.

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Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a sheet comprising thermoplastic resin, medical ingredient, and oily ingredient, and manipulate the amounts of the thermoplastic resin in order to achieve a particular modulus depending on the intended use of the sheet, motivated by the teaching of the reference that disclosed sheets can have non-limiting desirable characteristics depending on the material of the sheet, with reasonable expectation of success of the delivered sheet to have a particular modulus on stretching depending on its site of application to deliver active agent to the skin or hair from the sheet as desired by applicants.

8. Claims 1-3, and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/32567 ('567).

WO '567 teaches a sheet comprising:

Olefin resins or polyamide resin such as nylon 6, nylon 66, polyvinyl chloride, polyvinylidene chloride, polyvinyl acetate, polyacrylonitrile, polyester, polyethylene terephthalate, and polybutylene terephthalate that are disclosed by applicants as thermoplastic resin, (page 14, line 22 till page 15, line 22);

Cosmetic substance including whiting component and antiphlogistic component (page 20, lines 15-20);

Oily ingredient comprising natural oils and esters of fatty acids such as isopropyl myristate, and higher fatty acids (page 19, lines 11-19);

Thermoplastic elastomer comprising styrene, polyurethane, polyester that are disclosed by applicants as hard segment, (page 14, lines 5-15; page 15, lines 23-25); and polyester, ethylene-propylene-diene monomer terpolymer, polyethylene, and polypropylene that are disclosed by applicant as soft segment, (page 14, lines 5-15; page 15, line 15).

The reference disclosed that the sheet is not easily torn in the course of peeling off and does not cause any remains of the film on the surface of the skin during peel off and it is not sticky (page 6, lines 17-22).

The reference does not teach the amount of the thermoplastic resin and the medical ingredient or the modulus of the sheet.

It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect, such as the modulus. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the ratios and weight percents of the thermoplastic resin and the active ingredient instantly claimed are not considered to impart patentable distinction absent evidence showing unexpected and superior results. The prior art teaches the property of delivering active ingredients to the skin or hair from the sheet, as desired by applicants.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a sheet comprising thermoplastic resin, medical ingredient, and oily ingredient, and manipulate the amounts of the thermoplastic resin in order to achieve a particular modulus depending on the intended use of the sheet, motivated by the teaching of the reference that the disclosed sheets having the

thermoplastic resin and thermoplastic elastomer is not easily torn in the course of peeling off and does not cause any remains of the film on the surface of the skin during peel off and it is not sticky, with reasonable expectation of success of the delivered sheet to have a particular modulus on stretching depending on its site of application to deliver active agent to the skin or the hair.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali  
Examiner  
Art Unit 1615

*Isis Ghali*